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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,182	05/31/2007	Lai Albert	20366-023US1	7439

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EXAMINER	
TSAY, MARSHA M	

ART UNIT	PAPER NUMBER
1656	

NOTIFICATION DATE	DELIVERY MODE
08/20/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/574,182	ALBERT, LAI	
	Examiner	Art Unit	
	Marsha M. Tsay	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-39* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-39 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-12, 28, drawn to an isolated nucleic acid comprising at least 10 contiguous nucleotides of a polynucleotide sequence selected from the group consisting of: (a) nucleotides spanning positions 329 and 330 of the nucleotide sequences of clones 379-R8 and 379-RS3 shown in Figures 3A-3E, or its complement, and (b) consecutive nucleotides spanning positions 188 and 189 of the nucleotide sequence of clones 379-R4, 379-R5, 379-R2, 379-RS7 and 379-RS4 shown in Figures 3A-3E, or its complement.

Group II, claim(s) 13-16, drawn to an isolated polypeptide encoded within an open reading frame of a DKKL1 sequence selected from the group consisting of: (a) nucleotides spanning positions 329 and 330 of the nucleotide sequences of clones 379-R8 and 379-RS3 shown in Figures 3A-3E, or its complement, and (b) consecutive nucleotides spanning positions 188 and 189 of the nucleotide sequence of clones 379-R4, 379-R5, 379-R2, 379-RS7 and 379-RS4 shown in Figures 3A-3E, or its complement.

Group III, claim(s) 17-27, drawn to an isolated antibody or antigen binding fragment thereof, that binds to a polypeptide encoded within an open reading frame of a DKKL1 sequence.

Group IV, claim(s) 29-30, drawn to a method of screening for anticancer activity comprising providing a cell that expresses a DKKL1 gene encoded by a nucleic acid sequence selected from the group consisting of (a) nucleotides spanning positions 329 and 330 of the nucleotide sequences of clones 379-R8 and 379-RS3 shown in Figures 3A-3E, or its complement, and (b) consecutive nucleotides spanning positions 188 and 189 of the nucleotide sequence of clones 379-R4, 379-R5, 379-R2, 379-RS7 and 379-RS4 shown in Figures 3A-3E, or its complement, contacting a tissue sample derived from a cancer cell with an anticancer drug candidate, and monitoring an effect of the anticancer drug candidate on an expression of the DKKL1 polynucleotide in the tissue sample.

Group V, claim(s) 31, drawn to a method for detecting cancer associated with expression of a polypeptide in a test cell sample, comprising the steps of (i) and (ii).

Group VI, claim(s) 32, drawn to a method for detecting cancer associated with the presence of an antibody in a test serum sample, comprising the steps of (i) and (ii).

Group VII, claim(s) 33-34, drawn to a method for screening for a bioactive agent capable of modulating the activity of a DKKL1 protein, the method comprising combining the DKKL1 protein and a candidate bioactive agent; and determining the effect of the candidate agent on the bioactivity of the protein.

Group VIII, claim(s) 35-36, drawn to a method for treating cancers comprising administering to a patient an inhibitor of a DKKL1 protein.

Group IX, claim(s) 37-39, drawn to a method for inhibiting expression of a DKKL1 gene in a cell comprising contacting a cell expressing a DKKL1 gene with a double stranded RNA comprising a sequence capable of hybridizing to a DKKL1 mRNA corresponding to the polynucleotide sequences of (a) nucleotides spanning positions 329 and 330 of the nucleotide sequences of clones 379-R8 and 379-RS3 shown in Figures 3A-3E, or its complement, and (b) consecutive nucleotides spanning positions 188 and 189 of the nucleotide sequence of clones 379-R4, 379-R5, 379-R2, 379-RS7 and 379-RS4 shown in Figures 3A-3E, or its complement.

Additionally, each group named above is subject to further restriction. Applicant is required to further elect a specific clone. This is NOT an election of species. Nucleotide sequences encoding different proteins and/or polypeptides with different amino acid sequences are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequences are presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 USC 121 and 37 CFR 1.141. By statute, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the Examiner in his action shall require the Applicant…to elect that invention to which his claim shall be restricted." 37 CFR 1.142(a). See also CFR 1.141(a). It is noted that searching more than one of the claimed patentably distinct sequences represents a serious burden for the Office.

The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups I-IX appears to be that they all relate to a DKKL1 protein encoded by a nucleic acid comprising a nucleic acid sequence selected from the group consisting

of (a) nucleotides spanning positions 329 and 330 of the nucleotide sequences of clones 379-R8 and 379-RS3 shown in Figures 3A-3E, or its complement, and (b) consecutive nucleotides spanning positions 188 and 189 of the nucleotide sequence of clones 379-R4, 379-R5, 379-R2, 379-RS7 and 379-RS4 shown in Figures 3A-3E, or its complement; or wherein said DKKL1 protein is selected from the group consisting of (a) at least 4 consecutive residues spanning positions 108 and 109 of the polypeptide sequences of clones 379-R8 and 379-RS3 shown in Figures 4A-4B, and (b) at least 4 consecutive residues spanning positions 61 and 62 of the polypeptide sequences of clones 379-R4, 379-R5, 379-R2, 379-RS7 and 379-RS4 shown in Figures 4A-4B.

However, Krupnik et al. (1999 Gene 238: 301-313; IDS 06.14.10) teach a family of human Dkk proteins wherein said Dkk proteins have at least 4 consecutive residues spanning positions 108 and 109 of the polypeptide sequences of clones 379-R8 and 379-RS3 and/or at least 4 consecutive residues spanning positions 61 and 62 of the polypeptide sequences of clones 379-R4, 379-R5, 379-R2, 379-RS7 and 379-RS4. It should be noted that positions 108 and 61 are the amino acid residue lysine (K).

Therefore, the technical feature linking the inventions of Groups I-IX does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

Accordingly, Groups I-IX are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in

the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention or species.

Should applicant traverse on the ground that the inventions have unity of invention (37 CFR 1.475(a)), applicant must provide reasons in support thereof. Applicant may submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. Where such evidence or admission is provided by applicant, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is (571)272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marsha M. Tsay/
Examiner, Art Unit 1656

August 11, 2010